UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Renée Marie Bumb, Chief District Court Judge

TORRENT'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO CLARIFY WHETHER DR. NAGAICH MAY TESTIFY AS TO CERTAIN TOPICS WITH RESPECT TO WHICH PLAINTIFFS' EXPERT, MR. RUSS, HAS BEEN PERMITTED TO TESTIFY

TABLE OF CONTENTS

BACKGROUND 2

ARGUMENT 5

I. THE COURT'S RULING THAT DR. AFNAN SHOULD BE PERMITTED TO TESTIFY EQUALLY ON TOPICS ADDRESSED BY PLAINTIFFS' EXPERTS SHOULD EXTEND TO DR. NAGAICH. 5

II. DR. NAGAICH'S OPINIONS ARE BASED ON A RELIABLE METHODOLOGY AND ARE NOT INADMISSIBLE LEGAL CONCLUSIONS. 8

CONCLUSION 10

TABLE OF AUTHORITIES

Page(s)

Cases

Pfizer Inc. v. Teva Pharms. USA, Inc.,
461 F. Supp. 2d 271 (D.N.J. 2006).....9

Sheehan v. Del. & Hudson Ry. Co.,
439 F. App'x 130 (3d Cir. 2011).....8

In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.,
2020 WL 6887885 (E.D. Pa. Nov. 24, 2020).....9, 10

United States v. Lankford,
955 F.2d 1545 (11th Cir. 1992).....6, 7

Wolfe v. McNeil-PPC, Inc.,
881 F. Supp. 2d 650 (E.D. Pa. 2012).....9

At the September 18, 2024 hearing, the Court held that ZHP's expert, Dr. Afnan, should be permitted to testify about certain topics where Plaintiffs' experts have been permitted to testify on those same topics—even where Dr. Afnan had been previously precluded from testifying about those topics. The Court observed: "I can't have a plaintiff's expert opining as to a matter that the defendant's expert is not permitted to opine as to. . . . I'm not going to let, you know, your witness say one thing and not the other witness . . . [i]f the facts are disputed." Sept. 18, 2024 Hr'g Tr. 102:14-103:2 ("Tr.") (ECF No. 2858). That ruling should likewise apply to the testimony of Torrent's cGMP expert, Dr. Nagaich.

Both Plaintiffs and Torrent have designated an expert to opine on issues related to whether Torrent complied with cGMPs. Plaintiffs' expert is Mr. Russ; Torrent's expert is Dr. Nagaich. In the Court's prior ruling on the admissibility of liability expert testimony, the Court ruled that all of Mr. Russ's opinions and testimony is admissible under Rule 702. *See* Opinion on Liability Experts under *FRE* 702 at 25-27 ("Liability Op.") (ECF No. 2581). But when it came to Dr. Nagaich, the Court excluded certain of his opinions on ***exactly the same*** topics as those to which Mr. Russ will be permitted to testify. Excluding Dr. Nagaich from responding to Mr. Russ's opinions on those topics would be manifestly unjust, as the Court already ruled with respect to Dr. Afnan.

Accordingly, Torrent requests that the Court extend its holding as to Dr. Afnan to the testimony of Dr. Nagaich and allow him to testify as to all the topics disclosed in his expert report, which are directly responsive to Plaintiffs' expert Mr. Russ.[1]

BACKGROUND

On January 5, 2024, this Court issued an opinion addressing the admissibility under Federal Rule of Evidence 702 of the parties' liability experts' opinions. *See generally* Liability Op. The Court excluded several opinions from Torrent's cGMP expert, Dr. Nagaich. Those exclusions fall into two categories.

First, the Court excluded Dr. Nagaich's opinions addressing the qualifications of Dr. Jenny Yang, the independent, third-party auditor Torrent used to audit ZHP's facility that manufactured valsartan API. Liability Op. at 14; Expert Report of Akhilesh Nagaich, Ph.D. ¶¶ 73-78 ("Nagaich Rpt.") (ECF No. 2301-3). The Court reasoned that Dr. Nagaich's report was "silent as to how Yang is qualified" but noted that if he had "cited support for Yang's qualifications, the Court would not have precluded these paragraphs but rather viewed them as a credibility clash between Nagaich's opinions and Russ's." Liability Op. at 14. The Court did not find any

[1] To the extent necessary, Torrent also requests that the Court amend or modify the Court's prior order to make clear that no portions of Dr. Nagaich's intended testimony are excluded at trial.

problem with Mr. Russ's opinions on the same issue, his methodology, or the support he relied upon. Liability Op. at 25-27.

Mr. Russ's opinion as to Dr. Yang's qualifications cites a single document: an FDA establishment inspection report ("EIR") that observed that Torrent had not trained Dr. Yang regarding Torrent's specific standard operating procedure for API vendor qualification (SOP No. CQA-037). *See* Report of Philip Russ ¶¶ 116-18 ("Russ Rpt.") (ECF No. 2300-2) (citing TORRENT-MDL2875-00010961). Mr. Russ' methodology was simply to read and analyze the FDA's observations in this one EIR. *See id.* Dr. Nagaich's opinions use a similar methodology—analyzing record evidence based on his qualifications and experience—but rely upon a significantly broader set of materials. Specifically, Dr. Nagaich reviews and analyzes the same EIR Mr. Russ relies upon, but also Torrent's response and the FDA's subsequent recognition of the adequacy of that response. *Id.* ¶¶ 74-75. He also reviewed Dr. Yang's CV and her actual qualifications as an auditor as well as Torrent correspondence regarding those qualifications. *Id.* ¶ 73. Mr. Russ did not review any of this additional evidence. In other words, Dr. Nagaich used the same methodology as Mr. Russ but relied on a substantially more robust and complete record and was certainly not silent as to how Dr. Yang was qualified as an auditor.

The Court also excluded Dr. Nagaich's opinions regarding the outcomes of Dr. Yang's audit, based on its exclusion of Dr. Nagaich's analysis of Dr. Yang's

qualifications. Liability Op. at 14; Nagaich Rpt. ¶¶ 76-78. But, again, the Court permitted Mr. Russ to opine on the same issue and to offer his opinions regarding the significance of Dr. Yang's audit findings. *See* Russ Rpt. ¶ 119.

Second, the Court excluded several other portions of Dr. Nagaich's opinions regarding Torrent's compliance with industry standards and USP specifications. Liability Op. at 15; Nagaich Rpt. ¶¶ 79-80, 88-94, 95-97, 104. The Court held that each of these opinions were "legal opinion[s]" or "legal interpretation[s]." Liability Op. at 15. In each case, Mr. Russ opined on the same issues. *See* Russ Rpt. ¶¶ 45, 60, 71, 74, 106, 107. In fact, virtually all of Dr. Nagaich's opinions that were excluded as legal opinions are opinions that were offered ***in response to*** opinions proffered by Mr. Russ. *See* Nagaich Rpt. ¶ 79 ("Mr. Russ's opinion that 'Torrent had systemic, serious, and long-standing cGMP compliance violations that caused them to not identify nitrosamines in their Valsartan products' is inaccurate. On the contrary, Torrent had a long history of cGMP compliance.") (internally citing Russ Rpt. ¶ 45); Nagaich Rpt. ¶ 88 ("Mr. Russ suggests that Torrent observed unknown peak(s) in its residual solvent analysis of Valsartan API and Torrent ignored to do further analysis of anomalous peaks. . . . I disagree with Mr. Russ's assertion. It is not clear from the report as to which peaks Mr. Russ is referring to as anomalous. In my opinion, there were no sudden appearances of unknown peaks that would have triggered further investigation."); Nagaich Rpt. ¶ 90 ("Mr. Russ has argued that

'Torrent's cGMP API qualification system, laboratory control system related to API reduced testing and supplier auditing quality systems prevented from identifying unknown peaks as Novartis had done during industry standard API evaluation testing.' I disagree.") (quoting Russ Rpt. ¶ 71).[2] Dr. Nagaich's opinions regarding USP 467 and USP 469 were also excluded despite his analysis of those specifications being virtually the same as that of Mr. Russ. *Compare* Nagaich Rpt. ¶¶ 95-97, *with* Russ Rpt. ¶¶ 59, 63.[3]

ARGUMENT

I. THE COURT'S RULING THAT DR. AFNAN SHOULD BE PERMITTED TO TESTIFY EQUALLY ON TOPICS ADDRESSED BY PLAINTIFFS' EXPERTS SHOULD EXTEND TO DR. NAGAICH.

At the September 18 Hearing regarding Dr. Afnan, the Court observed: "I can't have a plaintiff's expert opining as to a matter that the defendant's expert is not permitted to opine as to. . . . I'm not going to let, you know, your witness say one thing and not the other witness . . . [i]f the facts are disputed." Tr. 102:14-103:2. That was correct; "fairness demands that if experts are presented, the jury must

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[2] *See also* Nagaich Rpt. ¶ 91 (quoting and responding to Russ Report ¶ 74); Nagaich Rpt. ¶ 92 (quoting and responding to Russ Report ¶ 106); Nagaich Rpt. ¶ 93 (quoting and responding to Russ Report ¶ 107); Nagaich Rpt. ¶ 94 (quoting and responding to Russ Report ¶ 108, although a citation to the Russ Report appears to be missing following the quotation).

[3] The Liability Opinion also excluded Nagaich Report ¶ 107, which is a summary of Dr. Nagaich's opinions and was excluded for the same reasons as applied to Dr. Nagaich's analysis discussed above. *See* Liability Op. at 15.

receive a full presentation on both sides of an issue." *United States v. Lankford*, 955 F.2d 1545, 1553 (11th Cir. 1992).

"It is an abuse of discretion 'to exclude the otherwise admissible opinion of a party's expert on a critical issue, while allowing the opinion of his adversary's expert on the same issue.'" *Id.* at 1552 (citation omitted). As the Court explained to Plaintiffs: "if you have a regulatory witness who is similarly situated as this witness and your witness can say that they were adulterated, it seems to me that given his expertise, which parallels your witness's expertise, he can say the opposite if his basis says it." Tr. 57:4-8.[4]

While the precise issues Dr. Nagaich was excluded from testifying about (auditor qualifications, audit results, compliance with industry standards, and USP requirements) are different from those that applied to Dr. Afnan (adulteration), the logic is the same. What is good for the goose is good for the gander. Dr. Russ and Dr. Nagaich offer opinions that are essentially two sides of the same coin. Mr. Russ opines that Dr. Yang was not qualified. Russ Rpt. ¶¶ 116-18. Dr. Nagaich opines that she was. Nagaich Rpt. ¶¶ 73-75. Mr. Russ opines that Dr. Yang's audit revealed concerns that Torrent did not adequately address. Russ Rpt. ¶ 119. Dr. Nagaich

[4] The Court further explained: "If the plaintiffs' witnesses are testifying in their regulatory capacity and they, given their regulatory expertise, opine that these drugs were adulterated before the FDA declared them adulterated, this witness will be permitted, given his expertise, to counter that." Tr. 60:7-12.

opines that Torrent properly followed up on those concerns. Nagaich Rpt. ¶¶ 76-78. Mr. Russ opines that Torrent did not comply with industry standards. Russ Rpt. ¶¶ 74-79, 104-114. Dr. Nagaich responds that Torrent did comply with those same industry standards. Nagaich Rpt. ¶¶ 79-80, 88-94, 104. Mr. Russ describes the requirements of USP 467 and 469 (although he does not cite the latter). Russ Rpt. ¶¶ 59, 63. Dr. Nagaich describes those very same USP requirements. Nagaich Rpt. ¶¶ 95-97. If Mr. Russ can opine on these topics, then Dr. Nagaich should be permitted to testify on those topics in response to Mr. Russ. Any other outcome would afford Plaintiffs favorable treatment.

In particular, although the Court excluded several of Dr. Nagaich's opinions regarding the qualifications of Dr. Yang and the audits she conducted because they lacked "support," the Court took no issue with Mr. Russ opining on those same topics based on a thinner evidentiary basis. Liability Op. at 14, 25-27; *supra* at 3-4. And while the Court also excluded Dr. Nagaich's opinions regarding Torrent's compliance with industry standards and the requirements imposed by USP 467 and 469 as either "legal opinion[s]" or "legal interpretation[s]," the Court took no issue with Mr. Russ opining that Torrent did not comply with industry standards or about the same USP requirements. Liability Op. at 15, 25-27; *supra* at 4-5. Not permitting Dr. Nagaich to testify on these topics would present grounds for reversal in the event of a verdict for Plaintiffs. *See Lankford*, 955 F.2d at 1551-52 (remanding for new

trial "[b]ecause the government was allowed to offer expert testimony on the reasonable tax implications of a 'campaign contribution,' but the defense was not").

In sum, Dr. Nagaich "should be permitted to testify what [Torrent] did, what [Torrent] didn't do, whether they followed the proper protocols, et cetera . . . ." Tr. 102:1-3. And, to the extent that requires amending or modifying the Liability Opinion, the Court has that power and should exercise it. "A trial judge has the discretion to reconsider an issue and should exercise that discretion whenever it appears that a previous ruling, even if unambiguous, might lead to an unjust result." *Sheehan v. Del. & Hudson Ry. Co.*, 439 F. App'x 130, 133 (3d Cir. 2011).

II. DR. NAGAICH'S OPINIONS ARE BASED ON A RELIABLE METHODOLOGY AND ARE NOT INADMISSIBLE LEGAL CONCLUSIONS.

Even putting aside the disparities in the Court's ruling, Dr. Nagaich's testimony should be admitted because he applies a reliable methodology and does not seek to offer inadmissible legal conclusions.

In terms of methodology, this Court held that Mr. Russ's methodology of reviewing "defendants' own documents" and "Torrent's own statements and conduct" is reliable. Liability Op. at 26. Dr. Nagaich did exactly what Mr. Russ did, and more: he reviewed the documentary evidence in this case, relevant regulations, relevant deposition testimony, interviewed Dr. Sushil Jaiswal (Torrent's Director of Quality), and reviewed reports of Plaintiffs' experts including Mr. Russ.

See generally Nagaich Rpt. ¶¶ 14, 71-72, 86, 87 & n.155, 105, Ex B. He also based his opinions on his extensive professional experience and knowledge of industry practice, including the eight years he spent as a principal investigator and drug quality reviewer at the FDA, where he received extensive training and experience in conducting cGMP compliance inspections of drug and biologic manufacturing sites. *Id.* ¶¶ 3-4. Dr. Nagaich's opinions about Dr. Yang's qualifications and audits are based upon the very same methodology the Court held was adequate as to Mr. Russ, and should therefore not be excluded.

In addition, Dr. Nagaich's testimony about Torrent's compliance with industry standards are not inadmissible legal conclusions. Courts in this Circuit and around the country "have repeatedly allowed FDA regulatory experts to testify regarding regulatory requirements." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 2020 WL 6887885, at *45 (E.D. Pa. Nov. 24, 2020); *see, e.g.*, *Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 658, 660 (E.D. Pa. 2012) (admitting testimony on "FDA regulation and [the defendant's] regulatory compliance"); *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 461 F. Supp. 2d 271, 278-79 (D.N.J. 2006) (admitting "general information regarding the FDA's regulation of prescription drug labeling" and the extent to which pharmaceutical company complied with it).

Dr. Nagaich's opinions are clearly permissible. They relate to Torrent's "long history of cGMP compliance" and the fact that Torrent's testing of valsartan API, auditing of ZHP, and use of a single API supplier are all consistent with industry standards based on Dr. Nagaich's extensive training in those standards and experience applying them in conducting inspections on behalf of the FDA. *See* Nagaich Rpt. ¶¶ 79-80, 88-97, 104, 107. All of this testimony is "helpful to the jury" "in light of the complex nature of the FDA [and regulatory] framework." *In re Suboxone*, 2020 WL 6887885, at *45. None of it crosses the line into telling the jury the result it should reach or telling the Court exactly how regulations should be interpreted. For this reason, too, the Court should clarify that Dr. Nagaich will be permitted to testify in full.

CONCLUSION

For the foregoing reasons, Torrent respectfully requests that the Court clarify that Dr. Nagaich may testify as to all topics disclosed in his expert report and, to the extent necessary, amend or correct its ruling on the parties' liability experts to allow Dr. Nagaich to so testify.

Dated: September 27, 2024

Respectfully Submitted:

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CERTIFICATE OF SERVICE

I, Alexia R. Brancato, an attorney, hereby certify that on September 27, 2024, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF and caused the unredacted version filed under seal to be served on all counsel of record by email.

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